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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,432

09/09/2005

Stephen I. Madden

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EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

09/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,432	MADDEN ET AL.	
	Examiner	Art Unit	
	SANDRA WEGERT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 14-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/25/06, 9/23/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1647

The examiner in charge of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner Sandra Wegert in Group Art Unit 1647.

Detailed Action

Status of Application, Amendments, and/or Claims

The Information Disclosure Statements, sent 25 January 2006, and 22 September 2008, have been entered into the record. Applicant's election of Invention I with the species *translocon-associated protein delta* (SEQ ID NO: 33), in the paper of 30 June 2008, is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 14-67 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Inventions or encompassing only non-elected species- and there being no allowable generic or linking claim.

The restriction requirement is deemed proper and is therefore made FINAL.

Claims 1-13 are under examination in the Instant Application.

Claim Rejections/Objections

Claim Rejections- 35 USC § 102

Art Unit: 1647

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 2 and 5-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Lal, et al (2001, J. Natl. Cancer Inst., 93: 1337-1343). Claims 1, 2 and 5-13 recite a method to aid in diagnosing glioma by detecting expression of at least one gene from 884 possible genes (see Claim 1). Applicants elected SEQ ID NO: 33, or "translocon-associated protein delta" as the first species for search. Lal, et al, also uses this gene and gene product to identify a human glioblastoma (also called "glioma").

Lal, et al list several genes that they disclose are overexpressed in dissected human glioblastoma cells (Table 1). One of those genes is "SSR4" or *translocon-associated protein delta*. They found a 2.3x increase in expression by PCR and attribute the gene's expression to the hypoxia that is present in most solid tumors. They used the exact same oligonucleotide tag used in the present application, namely SEQ ID NO: 33. They also measured RNA production by SAGE (p. 1338, 1st column), performed Western blots to detect protein production (p. 1338, 1st column), used tumors from human beings (see Abstract), compared cancerous tissue to normal tissue (p. 1338, column 1), and utilized immunohistochemistry (p. 1338) and microarrays (Fig 2). Lal, et al did not find that expression of translocon-associated protein delta was greater than 3X normal with any assay.

Art Unit: 1647

Claim Rejections - 35 USC § 112, first paragraph - enablement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for the limitations of the claims wherein expression of the gene to be detected in the claimed method is "five-fold higher" or "ten-fold higher."

Claims 3 and 4 are drawn to a method of measuring expression of selected genes in order to diagnose glioma, wherein expression is five-fold or ten-fold higher than normal. Applicants measured expression of the gene that hybridized to SEQ ID NO: 33, *translocon-associated protein delta*, using a cutoff threshold of 2-fold higher than normal (Specification p. 47, second paragraph), which is similar to that shown by Lal, et al (see above) who found expression was 2.3x normal (Table 1). Applicants have not shown expression of *translocon-associated protein delta* (or any gene) at the level of *five-fold* or *ten-fold* higher than normal, and thus are not enabled for these particular limitations in the claims.

Conclusion: Claims 1-13 are rejected for the reasons recited above.

Art Unit: 1647

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/

17 September 2008

/Elizabeth C. Kemmerer/

Primary Examiner, Art Unit 1646